

REMARKS

This paper is responsive to the Final Office Action issued May 13, 2009. Reconsideration and allowance of claims 2, 4, 6, 7, 9, 11-13, and 15-21 are requested.

The Office Action

Claims 2, 4, 9, 11, 12, 15, 18, and 20 stand rejected under 35 U.S.C. § 103 over Dewaele (US 7,065,235) modified by Ema (US 5,779,634), further modified by Nafstadius (US 2004/0005027).

Claims 6, 13, 15-17, 19, 20, and 21 stand rejected under 35 U.S.C. § 103 over Dewaele as modified by Ema, as further modified by Nafstadius, and further yet modified by Hochman (US 2003/0236458).

Claim 7 stands rejected under 35 U.S.C. § 103 over Dewaele as modified by Ema, as further modified by Nafstadius, as further yet modified by Washburn (US 6,379,306).

This Amendment Should Be Entered

This Amendment makes minor editorial changes to claim 18 (e.g., semicolons are changed to commas and the conjunction “and” added) to make it read easier without altering its scope.

The References of Record

Dewaele is directed to a radiographic scoring method. In medical scoring, each of various physical maladies is given a “score”. The score, for example, may be a number score, e.g., numbers zero through some higher number, indicative of the stage to which the malady has progressed, or the like. To give a simple example out of oncology, one score for a given tumor may be a score that denotes the size of the tumor. In order to score the tumor for size, Dewaele teaches that one should bring up a series of reference images which, in the present example, might be a series of circles or spheres of progressively greater size, each with a progressively higher score. The operator would then compare or overlay the spheres on the tumor to determine which one is a best match. The score for tumor size would be the number associated

with the best match circle or sphere. As another example, with tumors, the configuration of the surface is significant. For example, the tumor may have a smooth surface, e.g., a smooth sphere, or it may have various non-smooth surface configurations such as lumps or knobs on the surface, projections from the surface, yet longer projections or tendrils extending from the surface, etc. In order to score the surface configuration of the tumor, Dewaele teaches that one should bring up examples or reference images of the various tumor surfaces, each associated with a number or score. These reference images may be stylized drawings or could be an actual image from another patient which was decided, by a panel of experts, as the image of a tumor which ideally exemplifies the corresponding number or score. The operator then compares the image of the tumor to be scored with each of the reference images and selects the closest one. While the Dewaele method and apparatus is very nice for scoring various physical maladies, it is unrelated to the present application and claims.

Ema is merely exemplary of the acknowledged prior art, i.e., a large medical facility database in which image and other medical data from a large plurality of patients is stored. As discussed below, the present claims set forth a distinct improvement and advantages over a standard hospital database such as described in Ema.

If one were to combine the fair teachings of Ema with Dewaele, one would still have a radiographic scoring system in which the reference images, which may or may not be of a real patient and are certainly not of the same patient, are retrieved from a database and displayed concurrently with a diagnostic image. At best, Ema might suggest that the standardized score or reference images be stored in the hospital-wide database. However, because the standardized reference stage images for each score number are not diagnostic images of a patient in the hospital, it is doubtful that one reading Ema would even be motivated to store the reference stage images in the hospital central patient database of Ema.

Nafstadius is directed to a completely different field of medical endeavor relative to Dewaele. Nafstadius relates to radiation therapy or treatment planning (RTP). Because Nafstadius is directed to an improved piece of hardware, it gives little background concerning RTP. However, as is well-known in the art, when

a patient is to be treated with a radiation, for example to kill a tumor, a high energy radiation beam is focused precisely on the tumor and the tumor is irradiated from each of a plurality of different angles on each of a plurality of days. If the beam were applied from only one direction and the entire radiation dose applied in one session, the beam would kill all tissue along its length from the entry point into the patient to the exit point out of the patient.

To avoid this problem, before any radiation is applied, a three-dimensional diagnostic image of the patient is generated and that diagnostic image is segmented. That is, the image is segmented to identify the tumor, adjacent bones, and adjacent anatomical structures or tissues. This is typically a very time-consuming segmentation which often involves a large amount of manual input.

Once the image has been segmented, then a series of trajectories are planned which will pass the beam through the tumor from a plurality of different directions, yet avoid healthy tissues which are particularly sensitive to radiation. Also, the trajectories must be planned to avoid passing through bone before reaching the tumor or else the bone may absorb so much radiation that the tumor does not receive the expected dose.

The patient is then positioned in a radiotherapy machine, an exemplary one is disclosed in Nafstadius. Typically the patient is positioned in place with a variety of patient constraints which extremely accurately position the patient. The position of the patient and the constraints are noted, and often the skin of the patient is tattooed or semi-permanently marked with various reference points to be used in positioning the patient accurately in a prescribed relationship to the x-ray radiation beam.

As Nafstadius notes, over the course of the several days of radiation treatment, the tumor may shrink, the patient's bladder may be more or less full, and other physiological changes can take place. Again, in order for the radiotherapy to have the desired effect, the tumor must be in the expected location. To be sure that the tumor is in fact in its expected location, Nafstadius proposes to add an imaging device in order to make a relatively quick image of the tumor to be sure that it really is where it is supposed to be.

It is submitted that Nafstadius and Dewaele have no logical nexus or connection and both describe functions and systems which are commonly performed on different machines for different purposes to achieve different end results. How or why one viewing Nafstadius would be motivated to modify Dewaele is just not understood. To the contrary, it is submitted that Nafstadius does not teach the Examiner's proposed modification to Dewaele.

Hochman discloses a spectroscopic system and method which detects physiological properties in an area of interest by detecting changes in an intrinsic or extrinsic optical property of tissue in the area of interest. It is submitted that the Hochman machine has no logical nexus to Dewaele, Nafstadius, or Ema. Rather, the Hochman technique is performed with different equipment for different purposes and to achieve different end results than any of Dewaele, Nafstadius, and Ema.

Washburn, which relates to an ultrasound imaging system for generating color flow signals, again, has no logical nexus to Dewaele, Nafstadius, or Ema. The Washburn technique is performed using different equipment in a different way for a different purpose to produce different end results than any of Dewaele, Nafstadius, or Ema.

**The Claims Distinguish Patentably
Over the References of Record**

Claim 2 calls for numerous limitations not shown or fairly taught by the references of record. For example, claim 2 calls for:

a parameter extraction processor that extracts the parameter values from the selected region of interest of the at least one baseline image of the current patient and extracts like parameter values from the selected region of interest of the stored diagnostic images of the current patient or from data for generating the stored diagnostic images of the current patient.

Dewaele retrieves the standardized exemplars of the structure corresponding to each score. Dewaele does not retrieve or extract parameter values of the current patient. Ema, which merely shows a patient database, does not cure this shortcoming of Dewaele. Nafstadius teaches that one should generate an image to check the location of the tumor prior to each radiation therapy session. Because

Dewaele is scoring regions of an image, not performing radiotherapy, it is not clear what, if anything, Nafstadius teaches Dewaele. Whatever it might teach, it does not teach a parameter extraction processor as described above. Moreover, if one were to modify Dewaele to retrieve earlier images of the current patient rather than the standardized examples of each score, Dewaele would be rendered inoperative for its intended purpose.

Accordingly, it is submitted that **claim 2 and claims 4, 6, and 7 dependent therefrom** distinguish patentably and unobviously over the references of record.

Dependent claims 4, 6, and 7 contain yet additional distinguishing features. The Applicant reserves the right to discuss and assert these yet additional distinguishing features in a timely filed Appeal Brief, if necessary.

Claim 9 sets forth numerous limitations not shown by the references of record. For example, claim 9 calls for:

- selecting a region of interest of the subject on the displayed baseline diagnostic image representation;

- searching the subject database with the current subject identity and retrieving the diagnostic image representations of the current subject which include the selected region of interest ;

- extracting user selected parameter values from the selected region of interest of the displayed baseline and retrieved diagnostic image representations of the current subject;

- formatting the extracted parameter values from the retrieved and baseline diagnostic image representations into a report.

Dewaele shows none of these limitations. Rather, Dewaele describes retrieving standardized images exemplary of each potential score. There is no searching of a subject database with the current subject identity, no extraction of parameter values for the current patient, and no formatting of extracted parameter values into a report. Ema does not cure these shortcomings of Dewaele. Ema merely discloses a medical records database searchable by patient. There is no suggestion of searching based on the selection region of interest or extraction of parameter values, or formatting of extracted parameter values into a report. Nafstadius does not teach or fairly suggest modifying Dewaele to perform these steps. Indeed, Nafstadius does not

perform them either. Nafstadius does not search a subject database for other images of a selected region of a current patient or extract parameters from the selected region, or format the extracted parameter values into a report. Rather, Nafstadius generates an image to verify that the tumor is in the location that a radiation treatment plan expects it to be in before starting a radiation treatment session. Accordingly, it is submitted that **claim 9 and claims 11-13 and 15-17 dependent therefrom** distinguish patentably over the references of record.

The Applicant reserves the right to further discuss the additional distinguishing features in the dependent claims in a timely filed Appeal Brief, if necessary.

Claim 18 calls for one or more processors which perform the functions of:

- extracting selected parameter values from the image representation and storing them in the subject database,
- creating at least one other image representation of the portion of the subject on a subsequent date,
- extracting the selected parameter values from the at least one other image representation,
- storing the at least one other image representation and the parameter values extracted from the at least one other image representation in the subject database, and
- spatially registering the image representation and the at least one other image representation.

and claim 18 further calls for a monitor which performs the function of:

- displaying the image representations to show a time progression of the region.

Dewaele does not perform these steps. Rather, Dewaele retrieves the predefined standardized example of each score for manual comparison with a current image. There is no disclosure of performing the above-quoted steps nor of displaying a time progression of a selected region. Ema merely shows a large medical records database which is retrievable in various ways, but does not suggest any of the above-referenced steps or displaying image representations to show a time progression of a region.

Nafstadius teaches that prior to irradiating a tumor in accordance with a radiotherapy treatment plan, one should generate an image to verify the current location of the tumor. There is no suggestion in Nafstadius of performing the above-referenced steps nor of displaying image representations to show a time progression of the region. Moreover, if Dewaele were modified to display a time progression of a region rather than the standardized images which exemplify each score, then Dewaele would be rendered inoperative for its intended purpose.

Accordingly, it is submitted that **claim 18 and claims 19-21 dependent therefrom** distinguish patentably and unobviously over the references of record.

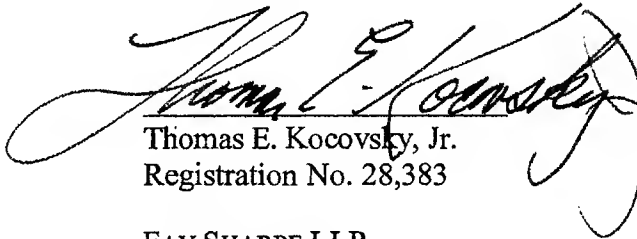
The Applicant reserves the right to present the additional distinguishing features set forth in the dependent claims in a timely-filed Appeal Brief, if necessary.

CONCLUSION

For the reasons set forth above, it is submitted that claims 2, 4, 6, 7, 9, 11-13, and 15-21 distinguish patentably over the references of record and meet all statutory requirements. An early allowance of all claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, the Examiner is requested to telephone Thomas Kocovsky at 216.363.9000.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Thomas E. Kocovsky, Jr.", is written over a horizontal line. The signature is fluid and cursive, with a large loop at the end.

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